REMARKS

I. INTRODUCTION

Receipt of the Office Action of April 16, 2003 is acknowledged.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

A. Amendments to the claims

Claims 1-7 and 12-37 have been previously canceled. Claim 38 has been canceled herein.

Claims 8, 9 and 11 have been amended in this application.

Claims 39-47 have been added.

Claims 8, 9 and 11 have been amended to more clearly and particularly claim the invention.

Claim 8 has been amended:

- to be drawn to --A vaccine vector-- rather than to "A vaccine comprising a vaccine vector", and to simply the language of the preamble;
- to amend part (b) to recite "a fragment comprising at least 12 consecutive amino acids from SEQ ID No:2, wherein the fragment defines an immunogenic epitope of Chlamydia". Support for this amendment is found at least at page 16, line 34 to page 17, line 12 of the specification;
- to delete part (c);
- to delete reference to the optional feature, which has been removed to new claim 39; and
- to add the limitation that "the nucleic acid molecule is operably linked to a promoter functional in a mammalian cell". Support for this amendment is found at least at page 25, lines 27-30, and page 29, lines 10-23 of the specification.

Claim 9 has been amended to depend on new claim 39, with consistent changes to the claim language.

Claim 11 has been amended to clarify that the claim is drawn to a vaccine which comprises the vaccine vector and a carrier.

New claims 40-43 are dependent claims which recite the further limitation that "the promoter is a viral promoter". Support for these new claims is found at least at page 24, lines 5-9, page 23, lines 29-34, page 26, line 17 to page 27, line 10, and page 29, lines 13-16.

New claims 44-47 are dependent claims which recite the further limitation that "the promoter is cytomegalovirus (CMV) promoter". Support for these new claims is found at least at page 29, line 14, as well as the Examples and Figures 3 and 4, which demonstrate an expression vector where the nucleic acid of the invention is operably linked to the CMV promoter.

Because these amendments and new claims do not introduce new matter, entry thereof by the Examiner is respectfully requested.

The Examiner is respectfully requested to also examine new claims 39-47, which are dependent on claims 8, 9 and 11.

Applicants retain the right to present claims drawn to the cancelled subject matter in a divisional application(s).

B. Rejection Under 35 U.S.C. § 112, First Paragraph-Enablement

The Examiner has rejected claims 8, 9, 11 and 38, alleging that the specification does not reasonably provide enablement for a pharmaceutical composition or a vaccine comprising SEQ ID NO:2, immunogenic fragment comprising at least 12 consecutive amino acids or polypeptide having 75% identity to SEQ ID NO:2. Applicants respectfully traverse.

Claim 38 is cancelled. The remaining claims have been amended to delete reference to sequences having 75% identity to SEQ ID NO:2. The rejection is thereby rendered moot with respect to this aspect of the claims.

The Examiner states that "The specification provides insufficient guidance of how to use the claimed vaccine to induce a protective immune response ... (s)ince no working

examples are set forth in the specification that the claimed nucleotide molecules encode a polypeptide which elicits protective immunity". Applicants point out that immunization *in vivo* using a DNA construct expressing SEQ ID NO:2, i.e. pCACRMP60 (Figure 3), resulted in immune protection (Table 1 and Figure 4), as shown by subsequent inoculation to test the ability of the vaccine candidate to limit the growth of a sublethal *C. pneumoniae* challenge.

In considering the *in vivo* results, the Examiner states that "challenging with sublethal amounts of C. pneumoniae does not establish a determination of protection". Applicants disagree. Use of a sublethal dose is necessary in the *in vivo* assay because a lethal dose of *C. pneumoniae* would kill both the vaccinated and control subjects, regardless of how effective a vaccine is. This is because bacteremia causes the subject to go into shock before the immune response could be launched. Use of a lethal dose is therefore not an effective way to distinguish a vaccine from a control. The mouse model used in the instant application is an accepted disease model; (see Murdin AD, Dunn P, Sodoyer R, Wang J, Caterini J, Brunham RC, Aujame L, Oomen R. Use of a mouse lung challenge model to identify antigens protective against *Chlamydia pneumoniae* lung infection. J Infect Dis. 2000; 181(suppl 3):S544-S551).

Applicants further point out that protective immunity has been defined at page 56, lines 3-4 of the specification "as an accelerated clearance of pulmonary infection". The Examiner is reminded that "The meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import; [...] A term used in the claims may be given a special meaning in the description." (See MPEP 608.01(o)). The specification clearly teaches what is claimed.

The Examiner quotes from *In re Wright* 999 F. 2d 1557, 1561, 27 USPQ 2d 1510, 1513 (Fed Cir. 1993) that a vaccine "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." Applicants submit that this standard has been met. The vaccine vector of the invention has not merely induced an antigenic response, i.e. merely triggered antibody production. The vaccine vector was actually shown to accelerate clearance of pulmonary infection in an accepted disease model.

In view of the above, Applicants submit that the claims as amended comply with the enablement requirement of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of the rejection are respectfully requested.

C. Rejection Under 35 U.S.C. § 112, First Paragraph-Written Description

The Examiner has rejected claims 8, 9, 11 and 38, alleging that the specification does not reasonably convey that Applicants have possession of the invention at the time the application was filed. Applicants respectfully traverse.

Claim 38 is cancelled. The remaining claims have been amended to delete reference to sequences having 75% identity to SEQ ID NO:2. The rejection is thereby rendered moot with respect to this aspect of the claims.

As stated above, Applicants have exemplified an expression construct containing a nucleic acid encoding SEQ ID NO:2. Applicants have also demonstrated that the claimed vaccine vector accelerates clearance of pulmonary infection in an accepted disease model.

The Examiner has stated that Applicants have not described a function which is shared by the 12 consecutive amino acids of SEQ ID NO:2. The claims have been amended to recite that "the fragment defines an immunogenic epitope of Chlamydia".

In view of the above, Applicants submit that the claims as amended comply with the written description requirement of 35 U.S.C. 112, first paragraph. Reconsideration and withdrawal of the rejection are respectfully requested.

D. Rejection of the Claims Under 35 U.S.C. § 102(b)

The Examiner has rejected claims 8, 9, 11 and 38 under 35 U.S.C 102(b) as being anticipated by Watson et al. 1995. Microbiology 141(10):2489-2497. Applicants traverse this ground for rejection.

Claim 38 is cancelled. The remaining claims have been amended to add the limitation that "the nucleic acid molecule is operably linked to a promoter functional in a mammalian cell".

Watson et al. discloses expression of the 9kDa and 60 kDa CrP genes in the 9/60 kDa CrP operon, by a shared promoter of *C. pneumoniae*. Watson et al. does not describe or

suggest expression of the 60 kDa gene by a promoter functional in a mammalian cell, as required by the claims. The promoter described by Watson functions in *C. pneumoniae*.

Reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) are respectfully requested.

II. CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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